TESTIMONY

 \mathbf{BY}

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THE SENATE AGRICULTURE, RURAL DEVELOPMENT,

AND RELATED AGENCIES APPROPRIATIONS

SUBCOMMITTEE

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Introduction

Chairman Kohl and members of the Subcommittee I am pleased to present the President fiscal year 2009 budget request for the Food and Drug Administration (FDA). I am joined by Mr. John Dyer, FDA Deputy Commissioner and Chief Operating Officer, and Mr. Richard Turman, Deputy Assistant Secretary for Budget at the Department of Health and Human Services.

At the outset, I want to lay out the trajectory reflected in FDA's budgets during my tenure. When I first sat before you on behalf of the FDA two years ago, I presented a budget that recognized the need for additional resources so that FDA can accomplish its mission. Just as important, FDA also recognized the need to establish plans that define how to use our resources wisely.

For the past two years, we requested additional resources to meet important public health challenges. We also developed detailed plans that communicate how we will deploy our resources to overcome the challenges that we face. However, you also expect performance while we are developing plans for the future, and we have delivered.

Recent FDA Achievements

Thanks to funding appropriated by this Subcommittee, FDA is achieving important public health milestones, and we thank you for your support. Since I appeared before you last year, FDA worked with Congress on the FDA Amendments Act (FDAAA) to

extend key user fee programs including the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee Act (MDUFMA), to reauthorize the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act. During the past year FDA also:

- published comprehensive plans for food defense, food safety, and import safety
- negotiated and signed food and medical product safety agreements with China
- expanded FDA\(\phi\) capacity to detect radiological contamination of food by 150 percent
- launched a national initiative to strengthen state food safety programs
- issued a current good manufacturing practices rule for dietary supplements
- approved a second-generation smallpox vaccine to enhance U.S. preparedness
- approved the first U.S. vaccine for humans against H5N1, the avian influenza virus
- approved the sixth seasonal influenza vaccine, allowing manufacturers to produce
 a record number of flu vaccine doses
- approved a decellularized heart valve, a new drug-eluting stent, and the first artificial cervical (neck) disk
- approved new treatments for hypertension, Crohnøs disease, cancer, HIV,
 diabetes, Parkinsonøs, Fibromyalgia, leukemia, and blood clotting disorders,
 including 22 new molecular entities and 18 orphan products
- tentatively approved the 64th anti-retroviral product under the President's
 Emergency Plan for AIDS Relief (PEPFAR)
- issued more than 680 generic drug approvals or tentative approvals during FY
 2007 ó a 30 percent increase from the previous year

- approved new tests for blood typing and to detect malaria, West Nile Virus,
 certain breast cancers, respiratory viruses, and other infections
- identified Critical Path opportunities for generic drugs and conducted Critical
 Path workshops on cancer clinical trials and developing anti-cancer agents
- proposed new standards and a new UVA rating for sunscreen products
- released a report on science and regulatory issues associated with nanotechnology
- conducted enforcement actions to protect consumers against unapproved drugs
 and devices and from unsafe dietary supplements
- identified 25 drugs products that must submit safety plans under Title 9 of FDAAA. These are important public health accomplishments, and they demonstrate FDAøs performance while we also prepare for the future.

My FDA colleagues and I recognize that we have important work to do in all FDA program areas. We also have challenges that cut across all FDA programs, such as expanding FDAøs reach beyond our borders, modernizing our Information Technology, and working with the General Services Administration to complete our new campus at White Oak.

FDA's 2009 Budget Request

The President FY 2009 budget request for FDA builds on the FY 2008 appropriation by proposing a 5.7 percent increase. FDA will focus its increased resources on protecting America food supply and improving the safety of human

and animal drugs, medical devices, and biologics ó including vaccines, blood products, and human tissues.

This increase will provide FDA with a budget of \$2.4 billion, which consists of \$1.8 billion in discretionary budget authority and \$0.7 billion in user fees. FDA user fee programs provide supplemental resources that not only allow FDA to review manufacturersøproduct applications but also ensure that Americans have access to safe and effective medical products.

As I mentioned, Congress reauthorized user fee programs for prescription drugs and medical devices last year in FDAAA. This year, the successful program to support animal drug review, the Animal Drug User Fee Act (ADUFA), expires on September 30, 2008. We have engaged with stakeholders to develop proposals to extend this program for an additional five years. FDA published a draft proposal for ADUFA II in the Federal Register and conducted a public meeting with stakeholders on March 11, 2008.

Finally, our budget includes \$48 million for four proposed user fees related to reviewing generic drugs, reviewing generic animal drugs, reinspecting facilities, and issuing export certificates for food and animal feed.

FDA Food Protection Plan Investments

On November 6, 2007, the Administration issued the Import Safety Action Plan (ISAP), a comprehensive, strategic roadmap to strengthen import safety. In conjunction with this release, FDA released its Food Protection Plan (FPP), a comprehensive initiative to protect America food supply.

The FPP is a risk-based, production-to-consumption strategy to assure the safety of domestic and imported food. FDAøs plan relies on three core elements ó prevention, intervention, and response ó and calls for ten new legal authorities. The plan is designed to identify potential food defense and food safety threats and to counteract those threats before they harm consumers.

FDA has begun implementing the FPP and ISAP with the resources that the Subcommittee appropriated in FY 2008. In FY 2009, FDA requests an additional \$42 million to protect the food supply and to continue to implement our plan. These funds will allow FDA to advance important food defense and food safety priorities. FY 2009 prevention activities include performing essential food research, determining the greatest threats of intentional and unintentional contamination to the food supply, and expanding food protection activities beyond our borders. Our intervention activities include conducting more risk-based inspections and surveillance and deploying new food defense and food safety screening tools. FY 2009 response activities include establishing more rapid response teams,

strengthening emergency response, and improving our ability to conduct food tracebacks.

To achieve these objectives and safeguard American consumers, FDA will also improve IT systems that support our research, risk assessment, inspection, and surveillance. Finally, FDA FY 2009 food protection initiative includes \$12 million for the cost of living pay increase for FDA food safety and food defense programs. These funds allow FDA to retain its professional workforce that conduct food safety and food defense activities. Overall, our food protection investments for FY 2009 support an additional 94 full-time equivalent (FTE) staff, including 68 FTE to conduct domestic and foreign inspections through FDA field operations in the Office of Regulatory Affairs.

Investments for Safe and Effective Medical Products

For FY 2008, Congress appropriated increases for drug safety, Critical Path, generic drug review, drug advertising review, and pandemic preparedness programs at FDA. With these increases, FDA will strengthen medical product development, safety, and review activities that the Subcommittee identified as FY 2008 priorities. I assure you that FDA will be a good steward of the funds you provide and that we will search for effective solutions to the public health challenges involving medical products.

For FY 2009, FDA is proposing a \$17 million initiative for medical product safety and development, including funds for the cost of living pay increase. FDA is also proposing targeted increases for our medical product programs.

With the FY 2009 increase, FDA & Biologics Program will strengthen its ability to prevent, detect, and respond to emerging safety threats in blood and blood products. FDA will also improve tissue safety by expanding our program to educate industry about tissue processing and tissue safety technologies.

In the Human Drugs Program, FDA will improve import safety by conducting additional investigations of criminal drug activity. The volume of drugs imported into the United States will likely increase by 12 percent during FY 2009, and the additional import volume creates a need for criminal investigators to support drug import surveillance.

In the Device and Radiological Health Program, FDA will strengthen import safety by improving the ability of the ORA field operations to work on import issues with Customs and Border Protection and other agencies. Finally, in the Animal Drugs and Feed Program, FDA will provide targeted grants to stimulate the development of new animal drugs under the Minor Use and Minor Species Animal Health Act of 2004.

Implementing FDAAA

In the fall of 2007, Congress enacted legislation reauthorizing prescription drug and medical device user fees, the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act. This legislation also grants new authorities to ensure the safety of the food supply and the safety and effectiveness of medical products ó drugs, devices, and biologics. As I mentioned previously, FDAAA also reauthorized user fees for prescription drug and medical device review.

Implementing FDAAA is a formidable challenge. The legislation is complex, with eleven titles containing more than 125 new requirements.

To cope with the breadth of this Act, FDA launched a detailed implementation plan. And, in the spirit of transparency, the details of our progress to implement FDAAA appear on our web site. Within FDA, we established working groups to confirm the scope of our FDAAA responsibilities and identify the actions and timetables necessary to conduct our new work. As you might expect, we are giving our first attention to FDAAA provisions that have the greatest implications for public health.

The new law is barely six months old, but our accomplishments are already tangible. As of today, FDA published 20 Federal Register notices related to FDAAA. We are methodically working through the new law, giving priority attention to new standards that will have the greatest public health impact. Achieving all of the goals and

objectives of this landmark legislation will require a sustained effort from many individuals inside and outside of FDA for years to come.

The Scope of FDA Challenges

FDA will face many challenges in the 21st century. Thanks to the talented professionals who serve the American public at FDA, we are addressing many daunting challenges within all areas of our mission. We must modernize our workforce, our work plans, and the infrastructure that supports our mission to assure that we remain the gold standard for food and drug regulation.

In this era of change, FDA has developed strategic plans to respond to high-profile challenges in priority areas. During the past two years, we presented comprehensive plans to Congress and the American public on food and import safety, and responded to the Institute of Medicine Report on drug safety.

My colleagues and I at FDA are committed to our mission and committed to the changes necessary to protect America public health. Thanks to your support, the FDA of the future ó the near future ó will better protect the public from the threats that we experience today. At the same time, FDA will better promote the discovery, development, and delivery of lifesaving products that improve the quality of our lives.

Conclusion

The FY 2009 request of \$2.4 billion contains essential resources to protect and promote the health and safety of the American public. The funds that we request will allow FDA to strengthen the safety of the food supply, to assess, review, and approve new products, and to better predict ó earlier and more accurately ó the safety and effectiveness of drugs, biologics, and medical devices.

With the FY 2009 resources, FDA will work to ensure that Americans enjoy the benefits of personalized medicine, a safe and wholesome food supply, and the promise of a better, healthier future. Meeting these challenges is only possible with your leadership and with the support that you consistently demonstrate for the mission of the Food and Drug Administration.

Thank you.